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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,336	01/10/2006	Cornelis Marius Timmers	2002.750US	8846
67706	7590	02/22/2010		
ORGANON USA, INC. c/o Schering-Plough Corporation 2000 Galloping Hill Road Mail Stop: K-6-1, 1990 Kenilworth, NJ 07033			EXAMINER O DELL, DAVID K	
			ART UNIT 1625	PAPER NUMBER
			NOTIFICATION DATE 02/22/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/540,336	<b>Applicant(s)</b> TIMMERS ET AL.	
	<b>Examiner</b> David K. O'Dell	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,4-7 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-7 and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>01/19/2010</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Claims 1, 4-7, 9-13 are pending in the current application.
2. This application is a national stage of PCT/EP03/51025 filed November 16, 2003 which claims priority to U. S. Provisional Application 60/435,040 filed December 20, 2002 and European Union Application (EPO) 2102866.7, filed December 20, 2002.

#### ***Request for Continued Examination***

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 19, 2010 has been entered.

#### ***Claim Rejections/Objections Withdrawn***

4. The rejection of method claim 16 for lack of enablement under 112 1<sup>st</sup> paragraph and other reasons is withdrawn since the claim is now canceled. The argument for patentability of claims 1, 4-7, 9-13, with respect to the double patenting rejection over the 10/540,335 application is accepted and the rejection is withdrawn. The claims have been amended in both cases such that the instant R3, R4 and R5 create patentable distinctions over the '335 claims.

#### ***Claim Rejections/Objections Maintained/ New Grounds of Rejection***

5. With respect to the double patenting rejection of claims 1, 4-7, 9-13 over the '707 application the rejection is maintained. Applicant's representative has argued that the 10/482,707 application claims do not literally overlap. This is the case, since the '707 application has had numerous amendments, however anticipation type double patenting is not the only type of

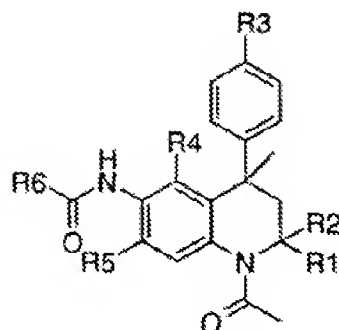
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obviousness type double patenting. There need not be literal overlap in the claims. The examiner followed the course set forth in MPEP 804 Definition of Double Patenting:

“A double patenting rejection of the obviousness-type>, if not based on an anticipation rationale,< is “analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103” except that the patent principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, \*>the< analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis.”

It may be that a further explanation is needed. The instant claim 1 is shown below:

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Formula I

or a pharmaceutically acceptable salt thereof, wherein

$R^1$  and  $R^2$  are H or Me

$R^3$  is H, hydroxy, (1-4C)alkoxy,

$R^4$  is H, OH, or (1-4C)alkoxy,

$R^5$  is OH, (1-4C)alkoxy or  $R^7$ ,

with the proviso that if  $R^4$  is H,  $R^5$  is not OH or (1-4C)alkoxy

$R^6$  is (2-5C)heteroaryl, (6C)aryl, (3-8C)cycloalkyl, or (1-6C)alkyl,

wherein the (2-5C)heteroaryl and the (6C)aryl are optionally substituted with one or more substituents selected from hydroxyl, amino, halogen, phenyl, (1-4C)alkyl, (1-4C)alkoxy, or (1-4C)(di)alkylamino,

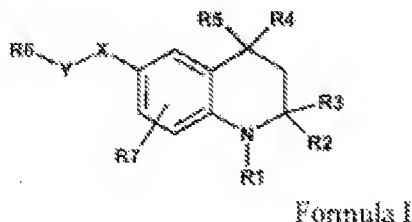
$R^7$  is amino, (di)(1-4C)alkylamino, (2-5C)heteroarylcarbonylamino, (2-5C)heteroarylcarbonyloxy,  $R^8$ -(2-4C)alkoxy,  $R^9$ -methylamino or  $R^9$ -methoxy

$R^8$  is amino, (di)(1-4C)alkylamino, (2-6C)heterocycloalkyl, (2-6C)heterocycloalkylcarbonylamino, or (1-4C)alkoxycarbonylamino and

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The copending genus of current claim 4 (as of April 13, 2009),

) A tetrahydroquinoline compound of Formula I,



R<sup>1</sup> is (1-6C)alkylcarbonyl;

R<sup>2</sup> and R<sup>3</sup> are (1-4C)alkyl;

R<sup>4</sup> is phenyl, optionally substituted with one or more substituents selected from the group  
hydroxy, (1-4C)alkoxy;

R<sup>5</sup> is (1-4C)alkyl;

Y-X is C(O)-NH,

R<sup>6</sup> is (1-6C)alkyl, (3-9C)heteroaryl

or phenyl, wherein phenyl is optionally substituted with

R<sup>7</sup> is H, (1-4C)alkyl, or (1-4C)alkoxy;

Since instant claim 1 has an apparent proviso there is not literal overlap, however the instant claims are drawn to compounds that have a very strong structural similarity the 10/482,707 application compounds, including the exemplified species claimed.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

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is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 4-7, 9-13, are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 7, 10-21, 23 of copending Application No. 10/482,707. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims overlap in scope substantially and cover the same compounds. The wording is only slightly different and the '707 application is broader but where X is NH and Y is CO the compounds of the instant case are produced. It is noted that some of the same species are present in both applications and only a proviso prevents literal overlap.

### **Determination of the scope and content of the prior art**

***(MPEP 2141.01)***

The '707 application teaches numerous compounds of the instant case that amount to change of the position of substituents, or other minor variations available within the general teaching.

***Ascertainment of the difference between the prior art and the claims***

***(MPEP 2141.02)***

The '707 application evidently does not expressly claim the compounds of the instant case, based on a proviso, but the general teaching provides the compounds of the instant case that are only minor variations.

**Finding of prima facie obviousness**

***Rational and Motivation***  
***(MPEP 2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare the compounds of the instant case. The compounds of the claims at hand are analogs of old compounds. One of ordinary skill would be motivated to make the compounds of the invention because he would expect the compounds to have similar properties, indeed we see that these compounds have the same properties. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary. *In re Grabiak* 226 USPQ 870, "[w]hen chemical compounds have "very close" structural similarities and similar utilities, without more



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a *prima facie* case may be made", *In re Deuel* 34 USPQ2d 1210, "a known compound may suggest its **analogs** or isomers, either geometric isomers (*cis v. trans*) or position isomers (emphasis added) (*e.g. ortho v. para*)".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The applications appear to have a common assignee.

### ***Conclusion***

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David K. O'Dell whose telephone

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number is (571)272-9071. The examiner can normally be reached on Monday-Friday 9:00 A.M. to 6:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JANET ANDRES can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David K. O'Dell/  
Examiner, Art Unit 1625

/Rita J. Desai/  
Primary Examiner, Art Unit 1625